

AUG 22 1996

K962155

Appendix A:

Summary of Safety and Effectiveness

I. General Information

Device Name:	Dental Tray for use with the Gill-Thomas-Cosman Relocatable Head Holder, a stereotactic head holder (for LINAC-based stereotactic radiotherapy)
Proprietary Trade Name	Gill-Thomas-Cosman (GTC) Dental Tray
Establishment Registration Number:	1222895
Classification:	Class II / Radiology
Performance Standard:	No applicable performance standards or special controls have been issued under section 514 of the Food, Drug, and Cosmetic Act.
Intended Use:	The Dental Tray holds an impression of the upper teeth, and is part of the GTC Relocatable Head Holder in stereotactic collimated beam, computer planned, LINAC (linear accelerator) based treatment. The Dental Tray holds the dental impression. The dental impression allows repeat positioning of the stereotactic frame at the same location, e.g., for multiple lower dose fractionated stereotactic radiotherapy treatments.
Predicate Device:	Dental Tray included in the Gill-Thomas-Cosman Relocatable Head Holder System K934523
Manufacturing Facility:	Radionics Software Applications 22 Terry Avenue Burlington, MA 01803 (617) 272-1233
Contact Name:	Amy LaForte, Ph.D.

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

A summary of the information contained in this 510(k) PMN that addresses safety and effectiveness follows.

General Safety and Effectiveness Concerns

RSA GTC Dental Tray labeling contains instructions for the proper use of this product. It includes a description of the product, directions for use, and applicable safety information. The testing provided in this 510(k) PMN, along with the instructions for use, ensure safe and effective use of the device when followed by the physician.

Description of the Device and Basis for Substantial Equivalence

The material of the GTC Dental Tray has been modified from that described in (K934523). The GTC Dental Tray addressed in this 510(k) PMN has the same intended use, design, and technological characteristics as the Dental Tray included in the commercially available GTC Relocatable Head Holder System (K934523). The Dental Tray holds an impression of the upper teeth as part of the predicate system. This impression allows repeat positioning of the stereotactic frame at the same location, e.g., for multiple lower dose fractionated stereotactic radiotherapy treatments.